references. In addition, the Office has pointed out that the Declaration filed September 17, 2001 does not identify the parent U.S. Patent application. A substitute Declaration is being obtained and will be forwarded to the Office. The §112 and 103 rejections are addressed below.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 9-14 stand rejected as not being enabled under § 112, first paragraph. The Office states that the Applicants do not provide a description or any working examples showing how the methods of the invention prevent dementia or Alzheimer's disease. Pointing to the Merck Manual at pages 1336-1340 (The Merck Manual, 15th Edition, published by Merck Sharp & Dohme Research Publishers, 1987) the Office argues that the etiology of the disorders is not known and that there are no known pharmaceutical agents which prevent such age related disorders. The Office also points to pages 366 and 369 of Sramek et al. (Drugs & Aging, 1999, 14(5), 359) to support the contention that there is no known evidence showing that COX-II inhibitors would prevent Alzheimer's disease. Applicants respectfully disagree with the Office's conclusions.

The law on enablement as clearly set forth by the Federal Circuit's predecessor court in In re Marzocchi, requires the Patent Office to provide specific reasons for a §112 rejection:

> As a matter of patent office practice...a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of §112 *unless* there is reason to doubt the objective truth of

> the statements contained therein which must be relied on for enabling support.
>
> ...
>
> It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

In re Marzocchi, 439 F.2d 220, 223-224 (C.C.P.A. 1971) (emphasis in the original). Furthermore, the evidence or reasoning supplied by the Office must be particularized and definite, not broad and general:

> [W]e do not consider that a broad allegation that the application disclosure is speculative, coupled with a recitation of various difficulties which might be encountered in attempting to put it into practice, and a further assertion that there might still be other difficulties which would not be foreseen, constitutes a sufficiently definite statement of a basis for rejection.

In re Chilowsky, 229 F.2d 457, 462 (C.C.P.A. 1956).

The compounds of the invention are inhibitors of COX-II and are useful for the prevention of various dementias. (See specification, page 3, lines 3-8, and claims 9-14). One possible mechanism for the preventive effect of the claimed compounds is through the ability of these compounds to block enzyme activity directly by acting as a substrate for the enzyme. (Specification, page 4, lines 10-17). The compounds of the invention may be administered for either prevention or treatment by a variety of techniques including oral, intravenous, intramuscular, subcutaneous, or intraperitoneal administration. (Specification, page 9, lines 10-11 and page 10, lines 4-33).

The references cited by the Office do not provide any evidence that contradicts Applicants' claims. The Merck article describes various types of dementia, their diagnoses, prognoses and treatment. Even if the article is read, as proposed by the Office, to indicate that there are no known pharmaceutical agents which prevent such age related disorders, this reading merely enforces the need for such compounds. It does not support an enablement rejection under 35 U.S.C. § 112.

Sramek et al., at pages 366, describes differences between COX I and COX II, including the high selectivity of COX-II inhibitors and the resultant ability of such inhibitors to be anti-inflammatory without having adverse effects typical of most anti-inflammatory drugs. Page 369 summarizes the article. The article does not discuss the preventive effect of COX II inhibitors on dementia. The article, therefore, does not provide any evidence that is inconsistent with the claimed invention and does not support an enablement rejection under 35 U.S.C. § 112.

Neither the Merck article nor Sramek et al. provides any evidence or reasoning that casts doubt on the objective truth of the statements contained in the application and the invention claimed in claims 9-14. Applicants respectfully submit that the claimed invention is enabled under 35 U.S.C. § 112, first paragraph. Accordingly, withdrawal of the § 112 rejection of claims 9-14 is respectfully requested.

First Rejection Under 35 U.S.C. § 103(a)

Claims 1-8 stand rejected under § 103 as being unpatentable over WO 96/11676 ("Ducharme") in view of U.S. Patent Number 5,760,068 ("Talley"). The Office states:

Ducharme teaches a method of treating a neurodegenerative disease by administering a COX-II inhibitor; benzenesulfonamide derivatives are known to be useful as selective COX-II inhibitors; and Talley teaches that compounds of the instant invention are known selective COX-II inhibitors (See Office Action, page 3, paragraphs 5-7). The Office concludes that it would have been prima facie obvious to employ the instant compounds as COX-II inhibitors in Ducharme's method. (Office Action, page 3, paragraph 7). While Applicants' do not agree with the Office's conclusion, the conclusion is irrelevant because Talley is not prior art to the instant application, under 35 U.S.C. § 103(c).

The Manual of Patent Examining Procedure discusses rejections under 35 U.S.C. § 103(c) and points out that:

> [e]ffective November 29, 1999, subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

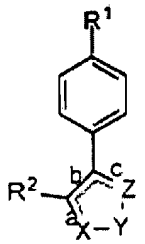
Manual of Patent Examining Procedure, Eighth Edition, Section 706.02(l)(1).

The subject application was filed July 2, 2001, and has an earliest priority date of April 3, 1997 based on U.S. Provisional Application No. 60/043,916. Therefore, the subject application qualifies under § 103(c). Talley issued as a patent on June 2, 1998. Since Talley issued after the earliest priority date of the instant application, Talley does not qualify as a prior art reference under 35 U.S.C. § 102(a) or (b) but can only be

considered prior art under 35 U.S.C. § 102(e). Thus if the rejection is proper, it must be one under §§102(e)/103.

Talley and the instant application were, at the time the subject matter of the claimed invention was made, subject to an obligation of assignment to the same person. Applicants have attached herewith a copy of the assignment record for the parent of the instant application indicating assignment to G.D. Searle & Co. Talley, as shown on its face, is also assigned to G.D. Searle & Co. Because the instant application and Talley are subject to an obligation of assignment to the same person, Talley is disqualified as prior art under § 103(c) and the rejection should be withdrawn.

Ducharme alone cannot support a § 103 rejection of claims 1-8. Ducharme relates to methods of treating neurodegenerative diseases, such as Alzheimer's disease, using non-steroid COX-II inhibitors of the following formula:



(Ducharme, page 4, lines 12-16). Ducharme does not disclose the pyrazolyl derivatives of claims 1-8, or the use of pyrazolyl derivatives as COX-II inhibitors, as recognized by the Office. (Office Action, page 3, paragraph 6). It follows that Ducharme does not disclose the use of Applicants' pyrazolyl derivatives in the treatment of dementia, as claimed. Therefore, claims 1-8

are not rendered obvious by Ducharme and withdrawal of the 35 U.S.C. § 103 rejection of these claims is respectfully requested.

Second Rejection Under 35 U.S.C. § 103(a)

Claims 1-8 stand rejected under § 103 as being unpatentable over U.S. Patent Number 6,136,839 ("Isakson"). While Applicants' do not agree with the Office's conclusion, the conclusion is irrelevant because Isakson is not prior art to the instant application, under 35 U.S.C. § 103(c).

As indicated above, the subject application qualifies under § 103(c) because it was filed after November 29, 1999. Isakson issued as a patent on October 24, 2000. Since Isakson issued after the earliest priority date of the instant application (April 3, 1997), Isakson does not qualify as a prior art reference under 35 U.S.C. § 102(a) or (b) but can only be considered prior art under 35 U.S.C. § 102(e). Thus if the rejection is proper, it must be one under §§102(e)/103.

Isakson and the instant application were, at the time the subject matter of the claimed invention was made, subject to an obligation of assignment to the same person. As discussed above, the instant application is assigned to G.D. Searle & Co. Isakson, as shown on its face, is also assigned to G.D. Searle & Co. Because the instant application and Isakson are subject to an obligation of assignment to the same person, Isakson is disqualified as prior art under § 103(c). Accordingly, withdrawal of the § rejection of claims 1-8 is in order and is respectfully requested.

Reconsideration and withdrawal of the rejections are respectfully requested. Should the Examiner believe that a discussion of this matter would be helpful, he is invited to telephone the undersigned at (312) 913-0001.

Respectfully submitted,

Dated: 11/27/02 By: _____

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